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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,481	01/20/2004	Nozer M. Mehta	P/546-280	2921

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EXAMINER	
RUSSEL, JEFFREY E	
ART UNIT	PAPER NUMBER
1654	
MAIL DATE	DELIVERY MODE
05/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/761,481	**Applicant(s)** MEHTA ET AL.	
	Examiner Jeffrey E. Russel	**Art Unit** 1654	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 10 May 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *10 May 2007*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See attachment*. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *NONE*.
   Claim(s) objected to: *NONE*.
   Claim(s) rejected: *1-63 and 65*.
   Claim(s) withdrawn from consideration: *NONE*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See attachment.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

1. The proposed limitation to claim 1 raises new issues requiring further consideration and search. This limitation has not previously been considered in conjunction with the composition claims. It is not clear what amount of patentable weight should be given to the proposed new limitation.

The proposed amendment to claim 45 raises new issues requiring further search and consideration with respect to dependent 48. The proposed amendment to the independent claim would result in dependent claim 48 reciting a method of amidating a peptide at the C-terminus where the peptide is not naturally amidated at the C-terminus, or would result in a method of amidating a peptide at the C-terminus where the peptide is also amidated at a site other than the C-terminus. Such a combination of limitations has not previously been claimed or searched. The proposed amendment to independent claim 45 raises new issues requiring further search and consideration with respect to dependent claim 61. The proposed amendment to the independent claim would result in a requirement for the LH-RH of dependent claim 61 to be amidated at a location that is not naturally amidated. The only possible sites for such amidation appear to be the sidechains of the Arg or His residues, which type of amidated LH-RH agents have not been previously claimed or searched. The proposed amendment to claim 45 raises new issues of duplicate claims with respect to instant claim 62, which recites the identical limitation proposed for claim 45.

2. The examiner agrees that the proposed amendment to claim 45 would overcome the rejections set forth in sections 4, 5, and 7 of the final Office action.

3. The examiner maintains his position for the reasons set forth in the final Office action.

4. Concerning the rejection set forth in section 6 of the final Office action, please note the first few words of the Abstract of Stern et al '918: "Bioavailability of peptide active agents to be administered orally is enhanced...". Stern et al '918 teaches the proposed required limitation for claim 1. Stern et al '918 do not teach that oral bioavailability is enhanced due to amidation of the peptide active agent at a site that is not naturally amidated. However, motivation to combine references under 35 U.S.C. 103(a) need not be the same as Applicants' motivation. See MPEP 2144, and especially In re Dillon, 16 USPQ2d 1897 (Fed. Cir. 1990). Concerning Applicants' argument at page 14, lines 8-10, Applicants have taken the examiner's argument out of the context in which it was made. This argument by the examiner was made as part of an anticipation rejection, and was not made as part of this obviousness rejection. With respect to claim 65, Applicants and the examiner disagree on this point. Stern et al 918's disclosure of compositions for enhancing the bioavailability of orally administered peptides is seen by the examiner to constitute motivation to administer any therapeutic peptides, including the PTH 1-34-OH of Barbier et al, using the forms taught by Stern et al '918. See, e.g., column 5, lines 55-59, and note especially the word "any". With respect to claim 45, the examiner disagrees with Applicants' summation of the issue. The examiner maintains that the issue is not whether "any" of the references suggest replacing peptides described in the '918 patent with a peptide which is amidated at a site that is not naturally amidated for the purpose recited in claim 45. Rather, the examiner maintains that the issue is whether all of the references taken as a whole suggest Applicants' claimed invention (see MPEP 2141.02(VI) and MPEP 2145(IV)), and the examiner maintains that motivation to combine the references need not be the same motivation that might be recited in Applicants' claims (see MPEP 2144, and Dillon).

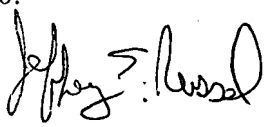
The rejection set forth in section 8 of the final Office action is maintained for reasons analogous to those set forth above.

5. The rejections set forth in sections 9-11 of the final Office action are maintained. The proposed amendment to claim 1 would not affect the examiner's position that references anticipate the claims. An intent motivation can not be relied upon to distinguish a prior art reference that teaches a claimed product. As long as a prior art product is capable of being administered orally, it does not matter that the prior art does not intend to administer the product orally.

6. The rejection set forth in section 12 of the final Office action is maintained. Oral delivery is explicitly taught in paragraph [0064] of Peri et al, and the only context in which oral delivery is taught is for the delivery of hPTH(1-34) amidated at its C-terminus. Oral delivery of peptides is well-known in the art, and the reference need not provide detailed disclosure of that which is well-known in the art. For evidence that oral delivery of peptides is well-known in the art, please see, e.g., U.S. Patent Nos. 5,206,219, 5350,741, 5,614,219, 6,086,918, and 6,673,574; AU-A-79394/87; European Patent Application 0 517 211; and WO Patent Applications 95/25534, 97/33531, and 00/07979; cited in Applicants' Information Disclosure Statement filed September 7, 2004. If Applicants have specific evidence demonstrating non-enablement of Peri et al, they should provide it. See also MPEP 2121.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

May 18, 2007